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Assessment of decontamination processes for dioxins and dioxin-like PCBs in fish oil by physical filtration with activated carbon

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Abstract

Following a request from the European Commission, the EFSA Panel on Contaminants in the Food Chain (CONTAM) provided a scientific opinion on the assessment of decontamination processes involving the adsorption with activated carbon and physical filtration of fish oil in order to reduce the amount of dioxins (polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) and dioxin-like polychlorinated biphenyls (DL-PCBs). All feed decontamination processes must comply with the acceptability criteria specified in the Commission Regulation (EU) 2015/786. Two feed business operators provided data on their respective decontamination processes, which were assessed in terms of the efficacy of the process and the absence of adverse effects in the nature and characteristics of the product after decontamination. The processes proved to be able to remove PCDD/Fs (82–95%) and DL-PCBs (26–45%) from the fish oil, depending on the process used by the business operator. Given that the level of contamination is within the range of the tested untreated fish oil, it is possible to meet EU requirements for these contaminants after decontamination. The CONTAM Panel considered both the evidence provided by one of the business operators and information in the available literature to conclude that the proposed processes do not lead to any detrimental changes in the nature of the fish oil. However, the process can deplete some beneficial constituents (e.g. vitamins). Information was provided to demonstrate the safe disposal of the waste material. The CONTAM Panel concluded that, on the basis of the information submitted by the feed business operators, the proposed decontamination processes to remove dioxins (PCDD/Fs) and DL-PCBs from the fish oil by means of activated carbon and physical filtration were compliant with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

Keywords: decontamination processes, feed, dioxins, PCDD/Fs, DL-PCBs, fish oil, physical filtration

Requestor: European Commission

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[1] provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive is prohibited.

Directive 2002/32/EC provides also that Member States are to ensure that measures are taken to guarantee the correct application of any acceptable detoxification process on products intended for animal feed and the conformity of those detoxified products with the provisions of Annex I of that Directive. In order to ensure a uniform assessment across the European Union of the acceptability of detoxification processes, acceptability criteria for detoxification processes have been established at Union level by Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council.

The acceptability criteria for detoxification processes established by the Regulation shall ensure that the detoxified feed does not endanger animal and public health and the environment and that the characteristics of the feed are not adversely altered by the detoxification process. The Regulation furthermore provides that the compliance of a detoxification process with those criteria shall be scientifically assessed by the European Food Safety Authority (EFSA) on a request from the Commission.

The Commission has received the following application referring to detoxification processes for assessment by EFSA of compliance with the acceptability criteria:

Feed to be decontaminated	Process	Contaminants of concern
Fish oil	Physical filtration with activated carbon	Dioxins and DL-PCBs

1.1.2. Terms of Reference

In accordance with Art. 29 (1) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority for an assessment of these detoxification process for compliance with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

1.2. Interpretation of the Terms of Reference

EFSA received from the European Commission requests for scientific opinions on the assessment of applications referring to feed detoxification processes to be compliant with acceptability criteria specified in the Commission Regulation (EU) 2015/786 of 19 May 2015[2]. In this context, the term detoxification is interpreted as either decontamination by removing the contaminants or by chemical or biological processes able to reduce the toxicity of the contaminants present. This scientific opinion assesses a joint application from two feed business operators for their respective decontamination processes using adsorption with activated carbon and physical filtration of fish oil in order to reduce the amount of dioxins (polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) and dioxin-like polychlorinated biphenyls (DL-PCBs). One of the two business operators had an additional distillation step following treatment with activated carbon.

The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that the Terms of Reference provided by the European Commission were clear and that the opinion for the assessment of these physical decontamination processes should mainly focus on data in order to:

- enable the assessment of the efficacy of the process to remove the contaminants from the feed batches to ensure compliance with the requirements of Directive 2002/32/EC, and

[1] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10–22.

[2] Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification process applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council. OJ L 125, 21.5.2015, p. 10–14.

- demonstrate that the decontamination process does not adversely affect the characteristics and the nature of the feed.

Information concerning the safe disposal of the removed part of the feed was also considered.

1.3. Additional information

The two feed business operators (Polar Omega A/S (referred to here as feed business operator 1) and Fiskernes Fiskeindustri Skagen A/S (referred to here as feed business operator 2)) have provided the European Commission with information referring to the proposed decontamination process and its effectiveness as laid down in Directive 2002/32/EC.

2. Data and methodologies

2.1. Data

The feed business operators have submitted information in support of their claim on the efficacy of the decontamination process consisting of the physical filtration of fish oil with activated carbon to lower the amount of dioxins (PCDD/Fs) and DL-PCBs. This set of documents included information on the detoxification processes, on filters, substances and equipment used for the physical decontamination procedures, on analytical data (certificates of analysis), on the Hazard Analysis Critical Control Point (HACCP) procedure and on the safe disposal of undesirable substances and materials (approval from relevant national authorities).

The CONTAM Panel based its assessment on the information provided (see section 'Documentation provided to EFSA') and published literature to address the Terms of Reference.

2.2. Methodology

The CONTAM Panel evaluated the acceptability of the proposed decontamination processes with regards to the relevant regulations, specifically Directive 2002/32/EC and Commission Regulation (EU) 2015/786 with their Annexes. The assessment is conducted in line with the principles described in the EFSA guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and following the relevant existing guidance from the EFSA Scientific Committee, as appropriate.

3. Assessment

3.1. Method of analysis

Feed business operator 1 submitted information on the analyses of PCDD/Fs, DL-PCBs and fatty acid composition in fish oils performed by an accredited laboratory (Eurofins, Ökometric GmbH). Feed business operator 2 submitted information on the analyses of PCDD/Fs, DL-PCBs performed at its own laboratory. The analytical laboratories have followed provisions of Commission Regulation (EU) No 709/2014 of 20 June 2014 amending Regulation (EC) No 152/2009[3] with regard to the determination of the levels of PCDD/Fs and polychlorinated biphenyls.

3.2. Decontamination process

The feed business operators have submitted sufficient information to assess the operation at the two different plants including data on PCDD/Fs and PCBs and schemes describing the decontamination process of the fish oil.

The removal of PCDD/Fs and DL-PCBs through adsorption on activated carbon from liquid media has previously been documented in the scientific literature (Eppe et al., 2005; Maes et al., 2005; Oterhals et al., 2007). The effectiveness of the procedure may vary depending on different factors such as the medium to be decontaminated, the impurity and its composition, and the use of specific activated carbon.

According to the literature, the adsorption of PCDD/Fs onto activated carbon is highly effective, being able to reduce the levels by up to approximately 95%. The elimination of DL-PCBs is less effective (depending specifically on the ortho-substitution and the planarity of the molecule) with an approximate level of decontamination of typically about 50% (Usydus et al., 2009).

[3] Commission Regulation (EU) No 709/2014 of 20 June 2014 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls. OJ L 188, 27.6.2014, p. 1–18.

3.2.1. Description of the processes

Feed business operator 1 uses a three-step process to decontaminate the fish oil: an evaporation step followed by addition of activated carbon and finally a filtration procedure to obtain the final product (see Figure 1). Technical specifications on the characteristics of the activated carbon used in the treatment of fish oil were submitted.

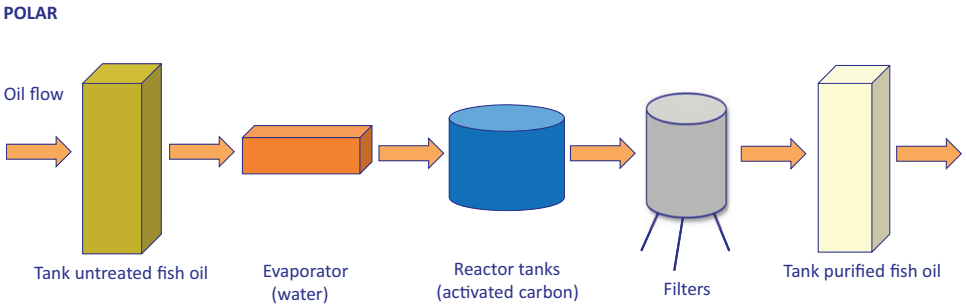


Figure 1: Schematic diagram of the decontamination processes of fish oils used by feed business operator 1

Feed business operator 2 pretreats the crude fish oil with cellulose which functions as a filter material. Activated carbon is added and the oil is subsequently filtered (stage 1). The oil may be further distilled which removes volatile components (deodorisation) and contaminants (stage 2). An overview of the decontamination process used is given below (Figure 2).

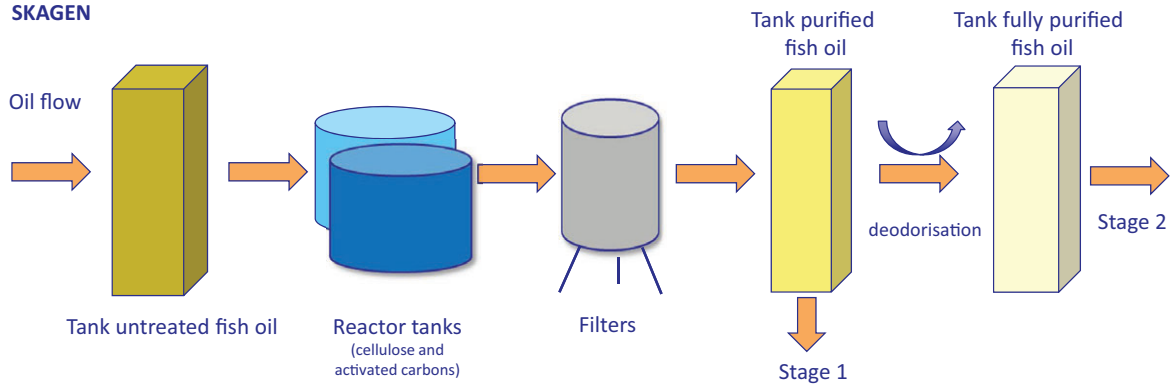


Figure 2: Schematic diagram of the decontamination processes of fish oils used by feed business operator 2

3.2.2. Efficacy of the process

According to the data provided by feed business operator 1, the decontamination process is able to decrease the total amount of PCDD/Fs and DL-PCBs by approximately 70% and of PCDD/Fs alone by more than 90% (Table 1). Data were provided on PCDD/Fs and DL-PCBs in seven batches of crude fish oil before processing, and in five batches taken after processing. Samples are taken from the tanks where the oil batches are mixed; therefore, data are not available from the same batch before and after processing.

Table 1: Levels of PCDD/F and DL-PCB in batches of fish oil before and after the decontamination process at feed business operator 1 (Documentation provided to EFSA No 1 and 2)

	Fish oil batches		Mean reduction (%)
	Before process (n = 7)	After process (n = 5)	
PCDD/Fs	7.01 (1.96)	0.38 (0.05)	95
DL-PCBs	8.75 (1.09)	4.80 (0.49)	45
Sum of above	15.76 (3.01)	5.18 (0.50)	67

PCDD/F: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCB: dioxin-like polychlorinated biphenyls; Average values expressed in ng WHO_{2005}-TEQ/kg; n: number of batches; () standard deviation.

PCDD/F and DL-PCB levels in crude fish oil ranged from 4.3–9.2 to 7.1–9.8 ng WHO_{2005}-TEQ/kg, respectively, and from 0.3–0.5 to 4.3–5.4 ng WHO_{2005}-TEQ/kg in decontaminated oil. The sum of PCDD/Fs and DL-PCBs in decontaminated fish oil was 4.7–5.8 ng WHO_{2005}-TEQ/kg when obtained from crude oil containing 11.4-18.9 ng WHO_{2005}-TEQ/kg (individual data in Appendix A).

The oil decontaminated at feed business operator 2 may undergo a two-stage process. After treatment with activated carbon (stage 1), the total amount of PCDD/Fs and DL-PCBs was reduced by approximately 50% and PCDD/Fs alone by approximately 80% (Table 2). After the additional distillation step (stage 2), the total PCDD/Fs and DL-PCBs was reduced by about 60% of the original level. The highest reduction in the second step was for DL-PCBs.

Table 2: Levels of PCDD/F and DL-PCB in fish oil before and after two stages of the decontamination process at feed business operator 2 (Documentation provided to EFSA No 2)

	Before process	After stage 1[(a)]	Mean reduction (%)	Range of reduction (%)	After stage 2[(b)]	Mean reduction (%)	Range of reduction (%)
PCDD/Fs	6.96 (3.5)	1.27 (0.57)	82	60–92	0.83 (0.30)	88	77–89
DL-PCBs	7.58 (3.85)	5.58 (2.25)	26	8–39	4.84 (1.50)	36	29–66
Sum of above	13.98 (8.3)	6.76 (2.8)	52	27–64	5.40 (2.96)	61	47–70

PCDD/F: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCB: dioxin-like polychlorinated biphenyls; Average values expressed in ng WHO_{2005}-TEQ/kg; () standard deviation.
(a): Stage 1 – treatment with activated charcoal: 11 samples before and after for PCDD/Fs, and 6 samples for DL-PCBs.
(b): Stage 2 – distillation: 4 samples for PCDD/Fs, 3 samples for DL-PCBs.

PCDD/Fs and DL-PCB levels in crude fish oil ranged originally from 1.3 to 13.3 and from 2.6 to 13.6 ng WHO_{2005}-TEQ/kg, respectively, and from 0.5 to 2.1 and 1.7 to 8.8 ng WHO_{2005}-TEQ/kg after the decontamination process (individual data in Appendix B).

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed and its updates sets action thresholds and maximum levels. Thresholds of action are needed to keep the presence of specific undesirable substances in products intended for animal feed as low as possible in order to reduce their presence in the food and feed chain. Where such action thresholds are exceeded, investigations must be carried out to identify the sources of the undesirable substances and steps taken to reduce or eliminate such sources. As shown in Table 3, the action threshold in fish oil for dioxins (sum of PCDDs and PCDFs) is 4.0 ng WHO_{2005}-TEQ/kg and the maximum level is 5.0 ng WHO_{2005}-TEQ/kg. For DL-PCBs, the action threshold in fish oil is 11.0 ng WHO_{2005}-TEQ/kg while the maximum limit for the sum of PCDD/Fs and DL-PCBs is 20 ng/kg. The levels of PCDD/Fs and DL-PCB in the decontaminated fish oils from both feed business operators were below the action thresholds (and maximum levels).

Table 3: Action thresholds and maximum levels for PCDD/Fs and DL-PCBs in fish oil according to Directive 2002/32/EC and its amendments

	Action thresholds	Maximum levels
PCDD/Fs	4.0	5.0
DL-PCBs	11	–
Sum of above	–	20

PCDD/F: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCB: dioxin-like polychlorinated biphenyls; Values expressed in ng WHO_{2005}-TEQ/kg, moisture content of 12%; –: not set in regulation.

3.3. Characteristics and nature of the fish oils

Certificates of analysis of three batches of fish oil taken before and after the process were provided by feed business operator 1 which provided data on the fatty acid profile and presence of peroxides, anisidine value, heavy metals (cadmium, lead and mercury), arsenic and chlorinated pesticides (including dichlorodiphenyltrichloroethane (DDT) and its metabolites, toxaphene, hexachlorobenzene, dieldrin and aldrin). None of these parameters were affected by the decontamination process. According to the literature, the physical filtration with activated carbon does not alter fish oil quality (Maes et al., 2005; Oterhals et al., 2007); however, it may remove some beneficial constituents (e.g. lipid-soluble vitamins

A, D and E (Lock et al., 2011)), that were not analysed in these fish oils. Feed business operator 2 did not provide data on the fatty acid profiles or other parameters referring to characteristics of the fish oil.

3.4. Disposal of the removed materials and filters

The feed business operators submitted information to demonstrate safe disposal of the waste material. The method of waste disposal from both operators has been approved by the Danish authorities (the Ministry of Food, Agriculture and Fisheries, and the Veterinary and Food Administration).

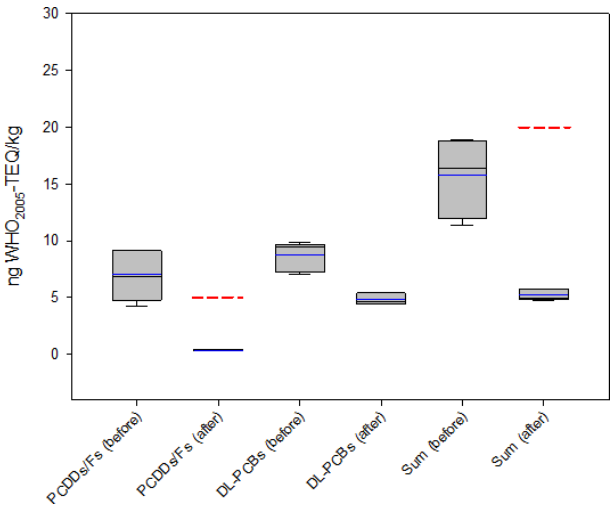
3.5. Discussion

The CONTAM Panel assessed all of the information made available in the various documents submitted by the feed business operators and was of the view that sufficient information to make an assessment of the proposed decontamination processes for PCDD/Fs and DL-PCBs in fish oil was available.

A short description of the processes with diagrams and operator manual were provided together with technical datasheet for the materials to be used. The Panel also considered that a good general knowledge for this type of procedure exists and was of the view that the proposed processes and related performances were assessable.

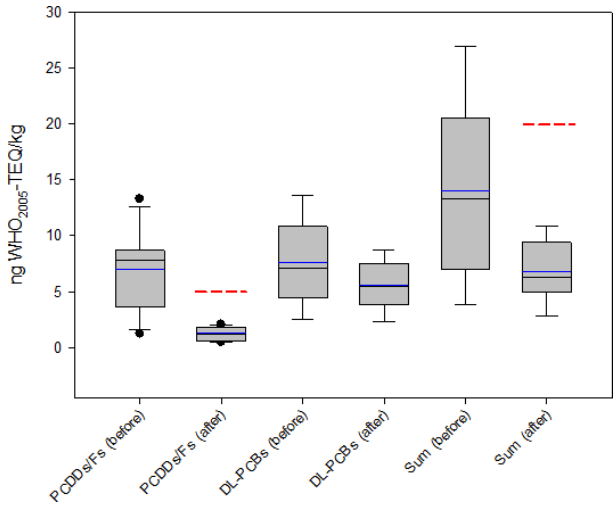
The available data enabled the CONTAM Panel to assess the quality of the analysis performed and to evaluate the efficacy of the decontamination process. In agreement with the scientific literature, the process was more efficient in removing PCDD/Fs than DL-PCBs (Eppe et al., 2005; Maes et al., 2005; Oterhals et al., 2007).

The amount of undesirable substances still in the feed after the decontamination process is compliant with the levels reported in the Annex I of Directive 2002/32/EC, falling below the legal limits including the action thresholds (Figures 3 and 4)



Black lines in box plots show the median and blue lines the arithmetic mean. Whiskers show 10th and 90th percentiles and the dots outliers. Red dashed lines indicate maximum limits in fish oil according to Directive 2002/32/EC and its amendments.

Figure 3: Graph representing analytical data from the tested fish oil batches at feed business operator 1



Black lines in box plots show the median and blue lines the arithmetic mean. Whiskers show 10th and 90th percentiles and the dots outliers. Red dashed lines indicate maximum limits in fish oil according to Directive 2002/32/EC and its amendments.

Figure 4: Graph representing analytical data from the tested fish oil batches at feed business operator 2 after stage 1 (additional reduction of levels after stage 2 is noted)

The amount of undesirable substances still in the feed after the detoxification process shall comply with the levels reported in the Annex I of Directive 2002/32/EC of the European Parliament of 7 May 2002. According to the Annex, the sum of PCDD/Fs and dioxin-like PCBs (sum of polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organization (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) for 'fish oil' shall not exceed 20.0 ng WHO-PCDD/F-PCB-TEQ/kg.

The Panel noted that the regular change of the filters might have an impact on the efficacy of the decontamination processes. This aspect is checked by the business operator 1 by monitoring the levels of PCDD/Fs and PCBs in the final product for every 1,000 tonnes of oil filtered and by business operator 2 for every batch of the product that is processed.

The CONTAM Panel concluded that it is possible to meet the current EU requirements for quality of fish oil with respect to these contaminants after filtration and adsorption using activated carbon. This assessment is based on the assumption that the levels of PCDD/Fs and DL-PCBs in untreated fish oil would be within the range of the tested batches.

Some experimental evidence was available from operator 1 that the treatment does not affect the fatty acid composition of the fish oil. In addition, the Panel considered the information available in the published literature demonstrating the absence of significant changes in fish oil composition characteristics after filtration with activated carbon (Maes et al., 2005; Oterhals et al., 2007).

Authorisations from the qualified national authority for the plants to carry out the decontamination processes according to the described methods are available. Documentation is also available for the disposal of waste materials.

The CONTAM Panel noted that it is the responsibility of the Member State to ensure that measures are taken to guarantee the correct application of any acceptable decontamination process on products intended for animal feed and the conformity of those decontaminated products with the provisions included in the Commission Regulation (EU) 2015/786 and its Annexes.

3.6. Uncertainty analysis

According to the interpretation of the Terms of Reference, the assessment of a physical decontamination process should mainly focus on the evaluation of the efficacy of the process to remove the contaminants and on the evidence that the characteristics and the nature of the product are not adversely affected.

Efficacy of the process: The method used is based on a well-established process that has been described in the scientific literature. There is little uncertainty that the process will be effective in removing certain contaminants from the product, however, the specific composition of the fish oil will

influence the efficacy of the process. There are some remaining uncertainties that may arise from the operation of the process, such as the regularity needed to change filters.

Characteristics of the product: The nutritional characteristics of the treated oil are supported by the analytical data on the fatty acid profiles of the fish oil before and after processing (Feed operator 1), however there is greater uncertainty for oil treated by feed operator 2 since no information was provided on the nutritional characteristics. Nevertheless, the scientific literature indicates that the process may remove some beneficial constituents (e.g. vitamins (Lock et al., 2011)). Whilst it is possible that the process may affect the nutrient composition, there is little chance that hazardous substances are introduced.

4. Conclusions

In relation to the Terms of Reference, the CONTAM Panel concluded:

- on the basis of the information submitted by the feed business operators the proposed decontamination processes are effective in reducing dioxins (PCDD/Fs) and DL-PCBs in the fish oil by means of physical filtration with activated carbon.
- the use of activated carbon adsorption does not lead to any detrimental changes in the nature of the fish oil through decontamination; however, it is possible that the process can deplete some beneficial constituents (e.g. vitamins).
- the proposed decontamination processes to remove dioxins (PCDD/Fs) and DL-PCBs from fish oil, were assessed to be compliant with the acceptability criteria provided in Commission Regulation (EU) 2015/786 of 19 May 2015.

Documentation provided to EFSA

1) Information provided by Polar Omega A/S and Fiskernes Fiskeindustri Skagen A/S to support the effectiveness of a detoxification procedure using physical filtration to remove unwanted substances from fish oil; June 2016.
2) Additional information submitted by Polar Omega A/S and Fiskernes Fiskeindustri Skagen A/S in response to a request from the EFSA CONTAM Panel; July 2017.

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Abbreviations

CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
DDT	dichlorodiphenyltrichloroethane
DL-PCBs	dioxin-like polychlorinated biphenyls
HACCP	Hazard Analysis Critical Control Point
PCBs	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-*p*-dioxins

PCDD/Fs	polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans
PCDFs	polychlorinated dibenzofurans
TCDD	tetrachlorodibenzo-*p*-dioxin
TEQ	TCDD Toxic equivalents
WHO	World Health Organization

Appendix A – Data analysis for feed batches: before and after decontamination process – Feed business operator 1 (Polar Omega)

Batch	Dioxins (PCDD/Fs) ng WHO_{2005}-TEQ/kg	DL-PCBs ng WHO_{2005}-TEQ/kg	SUM (PCDD/Fs) + DL-PCBs ng WHO_{2005}-TEQ/kg
	Before process	**Before process**	**Before process**
1b	9.16	9.66	18.82
2b	9.10	9.52	18.62
3b	9.03	9.84	18.87
4b	4.78	7.22	12.00
5b	4.27	7.09	11.36
6b	5.84	8.41	14.25
7b	6.89	9.49	16.38
Mean	7.01	8.75	15.76
SD	1.96	1.09	3.01
	After process	**After process**	**After process**
1a	0.47	4.50	4.97
2a	0.33	4.40	4.73
3a	0.33	4.33	4.66
4a	0.41	5.37	5.78
5a	0.36	5.42	5.78
Mean	0.38	4.80	5.18
SD	0.05	0.49	0.50

PCDD/F: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCB: dioxin-like polychlorinated biphenyls; WHO: World Health Organization; TEQ: TCDD Toxic equivalents.
Values expressed with 12% moisture.

Appendix B – Data analysis for feed batches: before and after decontamination process – Feed business operator 2 (FF Skagen)

Batch	Dioxins (PCDD/Fs) ng WHO_{2005}-TEQ/kg			DL-PCBs ng WHO_{2005}-TEQ/kg			SUM (PCDD/Fs) + DL-PCBs ng WHO_{2005}-TEQ/kg		
	Before	After stage 1[(a)]	After stage 2[(b)]	Before	After stage 1[(a)]	After stage 2[(b)]	Before	After stage 1[(a)]	After stage 2[(b)]
1	13.30	2.08	–	13.6	8.75	–	26.9	10.83	
2	8.7	1.8	1.3	7.8	7.1	3.8	16.45	8.93	8.36
3	7.8	1.5	–	–	–	–	–	–	–
4	10	1.9	–	–	–	–	–	–	–
5	6.53	1.17	–	–	–	–	–	–	–
6	5.19	0.58	0.58	–	–	–	–	–	–
7	1.26	0.50	–	2.58	2.29	–	3.84	2.79	–
8	8.58	1.66	–	–	–	–	–	–	–
9	8.5	0.58	–	9.94	6.04	–	18.44	6.62	–
10	3.05	1.21	0.71	5.05	4.35	1.72	8.1	5.56	2.43
11	3.63	0.92	0.76	6.55	4.93	4.64	10.18	5.85	5.4
Mean	6.96	1.27	0.83	7.58	5.57	4.84	13.98	6.76	5.40
SD	3.47	0.57	0.30	3.85	2.25	1.50	8.30	2.80	2.96

PCDD/F: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCB: dioxin-like polychlorinated biphenyls; WHO: World Health Organization; TEQ: TCDD Toxic equivalents.
–: Not available, values expressed with 12% moisture.
(a): Stage 1 – treatment with activated charcoal.
(b): Stage 2 – distillation.